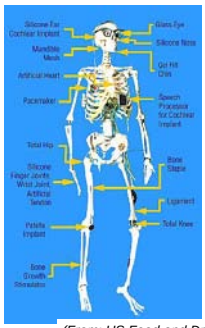
Biomaterials in Clinical Medicine

Anders Mølster and
Nils Roar Gjerdet

HELSE BERGEN
Haukeland University Hospital

innovest

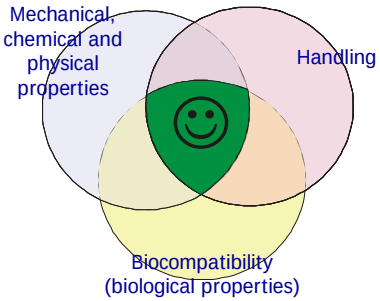
Biomaterials



Materials with the purpose of incorporation or implantation in humans to recreate or modify bodily functions.
(drugs not included)

(From: US Food and Drug Administration)

Heavy demands on biomaterials...



Influential industrial actors...

Smith+Nephew

DePuy
a Johnson & Johnson company

stryker Howmedica OSTEONICS

BIOMET The Most Responsive Company In Orthopaedics

STRATEC Medical

SYNTHES

Formal requirements in the EU-area

"Essential requirements"
in Medical Devices Directive (93/42/EEC)

↓

Conformity assessment

↓

CE

... basically a matter between the manufacturer and the bodies involved

How to evaluate bioimplants?

Research and development at the manufacturers

"Pre-marketing evaluation"

CE

marketing

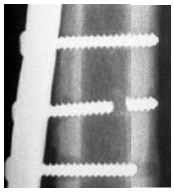
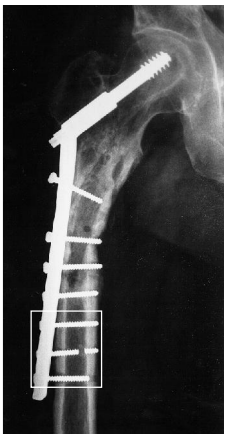
Specific quality testing and surveillance:
- laboratory studies
- clinical follow-up (e.g. registries)

"Post-marketing evaluation"

The use of (orthopedic) artificial materials is extensive

- In Norway, 40 000 fractures are operated each year (6% removed)
- 7000 hip prostheses
- 2400 knee prostheses are implanted

Orthopedic biomaterials with mechanical function

Orthopedic Biomaterials Project

ORTHOPEDIC BIOMATERIALS PROJECT

Need for manufacturer-independent research

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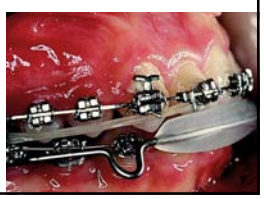
Haukeland University Hospital

Dentistry: Long tradition of development and evaluation of materials

- University: Dental Biomaterials
- NIOM: Scandinavian Institute of Dental Materials

Biomaterials - a meeting point between disciplines



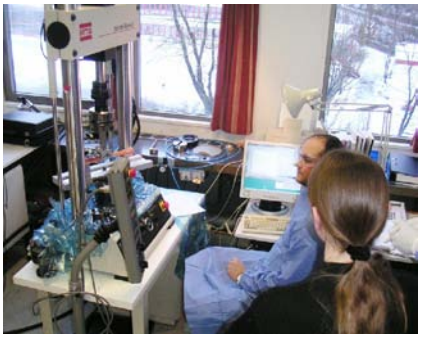
Purpose

- Device product control
- Evaluate potential adverse reactions
- New developments : Design; Evaluation methods; Tissue engineering; Nanomaterials ...
- Teaching (PhD, post graduate, clinical specialization)

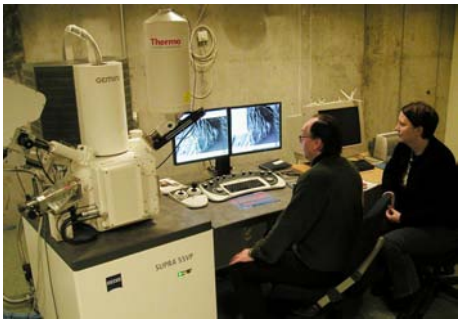
Methods

- Mechanical evaluation and testing
- Chemical evaluation
- Biologic evaluation
- Clinical evaluation

Advanced mechanical testing equipment



Advanced imaging



Field emission scanning electron microscopy
(Electron Microscopy Lab - UoB)

Advanced chemical analysis

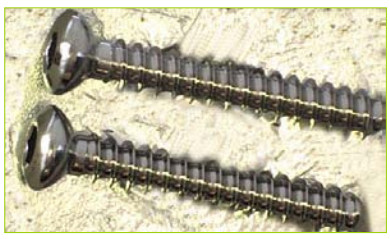
Inductively coupled plasma –mass spectrometry (ICP-MS) with laser ablation unit.
(Inst. Geosciences –UoB)

Examples: Projects and activities

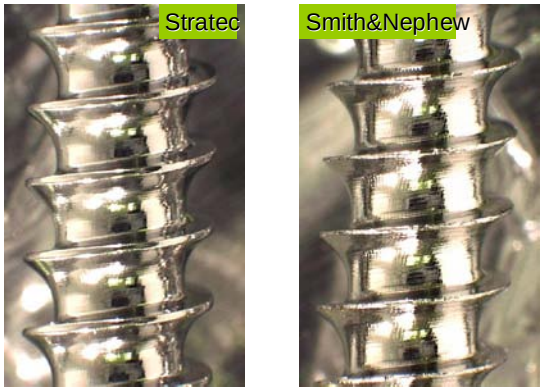
ORTHOPEDIC BIOMATERIALS PROJECT

Bone screws

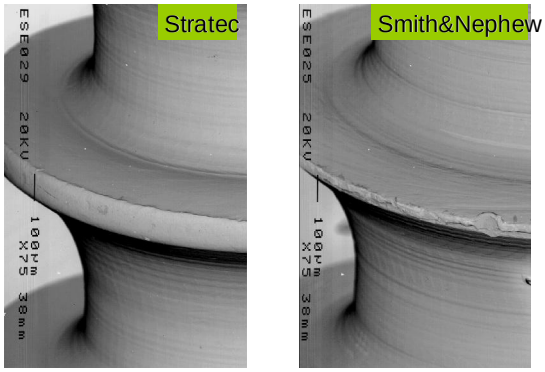
Quality control of 3,5 mm cortical screw from two manufacturers; Stratec (Synthes) vs. Smith & Nephew



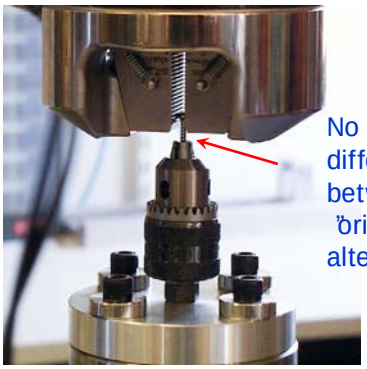
Surface finish: optical



Surface finish: SEM

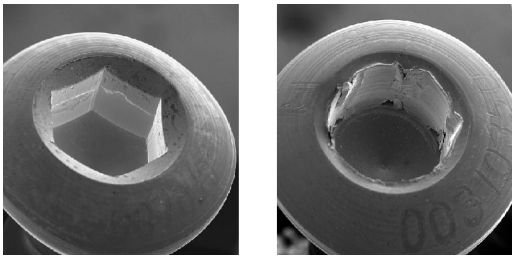


Mechanical testing



No major differences between the "original "and the alternative

Screw driver slippage
- a trivial everyday clinical problem

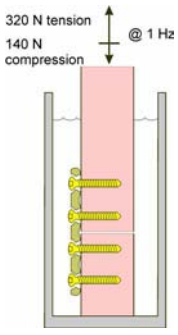


Corrosion of loaded osteosynthesis devices

- Mechanical cycling in different electrolytes
- Analysis of liquid as well as particles
- Inspection of implant surfaces

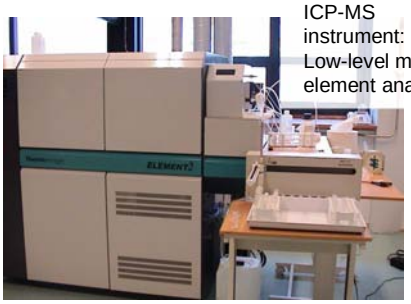
Combination of stainless steel and titanium?

Preliminary results:
No increased corrosion



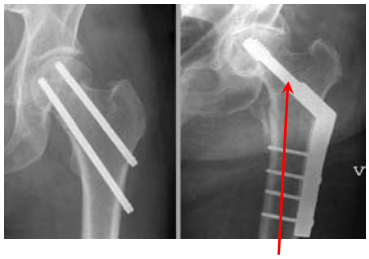
Clinical trace element analyses: Demanding techniques

Paul J. Høl, PhD



ICP-MS instrument: Low-level multi-element analyses

Clinical project: Level of systemic exposure following different hip fracture implants

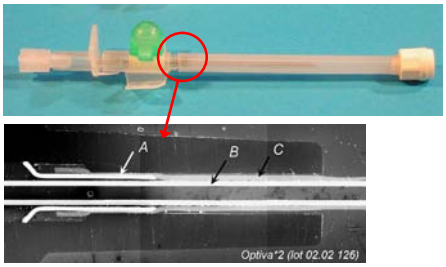


Higher release from sliding hip screw

Accidental finding: Intravenous catheters released substantial amounts of nickel

- Some patients showed high nickel concentrations in blood
- The values were found to be associated with routine infusion of Ringer acetate

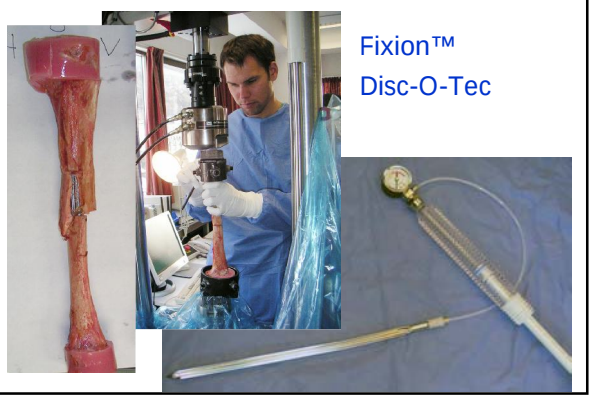
The catheter had a nickel-plated funnel inside …



Highlights the need for quality surveillance

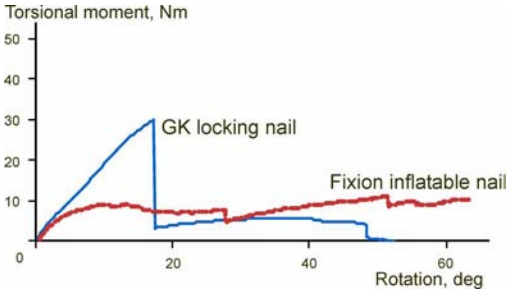
(Høl PJ & al Scand J Clin Lab Invest 2005; 65: 221-5)

Testing of inflatable nail



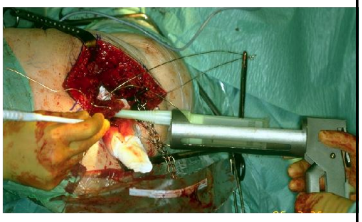
Fixion™
Disc-O-Tec

… lower maximum moment, but no sudden fracture

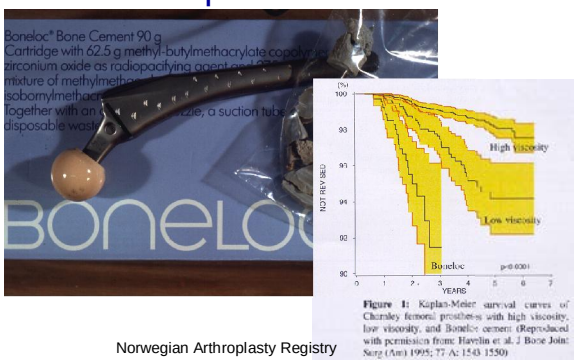


(Norwegian Association for Surgeons - Oslo, Oct 24-28, 2005. Abstract 206)

Bone cements - can we predict clinical performance?



Clinical survival of cemented prostheses



Norwegian Arthroplasty Registry

Bone cements

- Mechanical and structural characterization
  - –of new cements
  - –of retrieved cements
- Effects of testing conditions
- Correlation with clinical data

Preparation of specimens from retrieved cement

Bone cements change properties over time

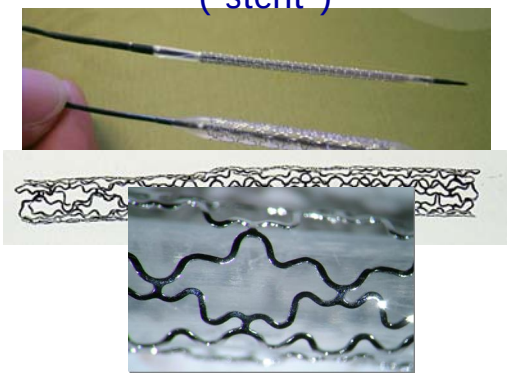
(Data in the publication process)

Going further ...

New hip prosthesis stem design

Easy removal of femoral stems in hip revision surgery

Not only orthopedics ("stent")



Nanotechnology and nanomedicine is a "hot topic"

- New materials and devices?
- Safety concerns?

U.S. Food and Drug Administration

USA – Food and Drug Administration: www.fda.gov/nanotechnology

Europe – European Commision: http://cordis.europa.eu/nanotechnology/nanomedicine.htm

Slow introduction of nanotechnology for medical devices ...

NanOss™: The first and only nanosurfaced medical device to be FDA approved (April 2006)

Ångstrom Medica

Immunologic and cellular responses to nanoparticles

- Few immunological reactions to nano-materials: Is this good or bad?
- In-vitro tests in progress

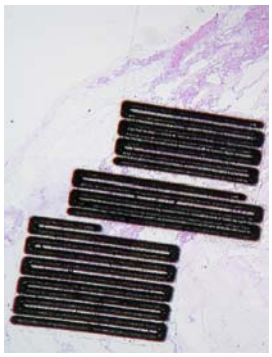
Particle exposure

Particles –ranging from nanosize to microsize –are present in tissue

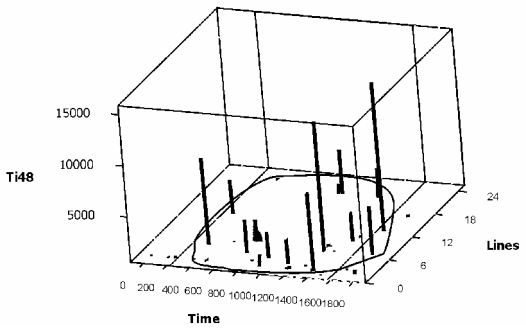
(Photo: Finnur Snorrason, Ullevål University Hospital, Oslo)

Detection of metal (particles) in tissue

- Laser ablation technique
- Vaporization of tissue with subsequent detection of elements



Titanium in oral mucosa



Challenges

- Bio-response to new materials and designs
- Continous surveillance of materials and procedures
- Contribute to development of new materials
- Continue the close cooperation with the clinical disciplines by establishing a laboratory at Haukeland University Hospital

External and internal collaborators, so far:

- Norwegian Arthroplasty Registry
- Centre for Element and Isotope Analysis, Faculty of Sciences, UoB. Analytical facilities, ICP-MS, laser ablation
- Orthopaedic Research Laboratory, Prince of Wales Hospital, Sydney, Australia. Micro-CT analyses of cement samples
- Clinical Research Centre in Dentistry –Oral implantology, UoB. Oral implant model (titanium)
- Laboratory for Clinical Biochemistry, Helse Bergen/UoB. Immunologic diagnostics
- Department of Orthopedic Surgery / Haukeland University Hospital –HUH, Kysthospitalet Hagevik

Thank You!

anders.molster@kir.uib.no
gjerdet@odont.uib.no
paul.hol@odont.uib.no

www.uib.no/orthopmat